SUMMARY OF THE REGULATORY COORDINATION COMMITTEE MEETING JUNE 29, 1999

The Regulatory Coordination Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Tuesday, June 29, 1999, at 1 p.m. Eastern Daylight Time (EDT) as part of the Fifth NELAC Annual Meeting in Saratoga Springs, NY. The meeting was led by its chair, Dr. Carl C. Kircher of the Florida Department of Health, Bureau of Laboratories. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The purpose of the meeting was to discuss items of interest as set forth in the committee agenda distributed prior to the meeting.*

INTRODUCTION

Dr. Kircher called the meeting to order with a welcome and a brief review of the ground rules for the meeting. He then put forth the motion that Dr. Michael Miller, of the New Jersey Department of Environmental Protection (NJDEP), be elected chair of the Regulatory Coordination Committee. There being a second and no objections, the motion was unanimously passed. Dr. Kircher recognized Dr. Harry Otto as he rotates off the committee for his meritorious service to the Regulatory Coordination Committee. After a review of Regulatory Coordination minutes from the Fourth NELAC Interim Meeting in January 1999 and the committee's May 5, 1999, meeting by teleconference, both minutes were approved by the committee pending minor corrections in contact information for Dr. Harry Otto and Ms. Ilona Taunton.

DISCUSSION OF INTERNATIONAL STANDARDIZATION ORGANIZATION (ISO) DRAFT 17025

Dr. Kircher distributed a hand-out constituting a draft report to the NELAC Quality Systems Committee summarizing the content of ISO draft standard 17025. This draft standard has been proposed as a revision to, and reissue of, ISO Guide 25 as the international standard for assessing the competence of testing and calibration laboratories. It will be voted upon for approval by the international laboratory community within the next several months. The draft report distributed by Dr. Kircher summarizes six major changes to ISO Guide 25, their impact on NELAC Chapter 5 (Quality Systems), and new or modified language in ISO 17025 that the Quality Systems Committee may want to consider for inclusion in NELAC Chapter 5. The six major changes reflected in ISO 17025 are summarized as follows:

- Alignment of sections to be more consistent with ISO 9001 and ISO 9002.
- Increased emphasis on laboratories to assess measurement uncertainties and to control result variabilities.
- Inclusion of sampling requirements to go with calibration and testing requirements.
- Inclusion of validation standards for performance-based measurement systems (PBMS).
- Allowances for expressing opinions and interpretations in test reports.
- Elimination of the detailed list of what laboratories must have in their quality manuals.

As Dr. Kircher briefly reviewed the new or modified language in ISO 17025 on a section-by-section basis, moderate discussion ensued. Committee members emphasized that ISO 17025 is a *draft* standard and that, if approved, will be reissued as a final standard. A participant commented that since ISO 17025 does address sampling issues, the Regulatory Coordination Committee should consider forwarding their report to the proposed NELAC Field Activities Committee if approved as a standing committee. This recommendation met with approval from the committee. Another participants asked for clarification of whether PBMS is included in Section 5.4.5 (Validation of Methods) and was reassured that it is included. A committee member noted that Sections 5.4.6 (Best Measurement Capability) and 5.4.7 (Estimation Uncertainty of Measurement), which probably apply more to calibration laboratories than to testing laboratories, are areas of dissent within the international community.

DISCUSSION OF U.S. ENVIRONMENTAL PROTECTION AGENCY (USEPA) REGULATORY AGENDA

Dr. Kircher distributed a hand-out constituting those items on the April 1999 USEPA Regulatory Agenda pertinent to laboratory accreditation. The semi-annual regulatory agenda is issued in April and October and is available on the Internet at *http://ciir.cs.umass.edu/ua*. A committee member noted that a proposed rule for Safe Drinking Water Act (SDWA) analytes was not included in the April 1999 regulatory agenda. It was conjectured that this rule was proposed after the April 1999 agenda had been set and would appear on the October 1999 regulatory agenda. Dr. Kircher moved that the April 1999 regulatory agenda be approved for submitting to the USEPA for posting on the NELAC Internet site. The motion was seconded and unanimously approved by the committee.

REGULATORY COORDINATION MATERIALS POSTED ON NELAC WEBSITE

Dr. Kircher distributed a third hand-out constituting a compendium of fields of testing by program-method-analyte for proposed inclusion on the NELAC Internet site. The list generated considerable committee discussion. One committee member noted that although NELAC accreditation will be on a program-method-analyte basis, the NELAC Program Policy & Structure Committee has not gone farther in defining the full scope of accreditation available under NELAC. The committee member stressed the importance of defining these Fields of Testing for establishing reciprocity between states. Several committee members noted that this issue had also come up in recent NELAC Transition Committee and Proficiency Testing Committee meetings and would probably be addressed at length in the upcoming Environmental Laboratory Advisory Board (ELAB) meeting. Another committee member suggested that this situation is symptomatic of a move in NELAC toward implementation without already having in place the infrastructure necessary for implementation. Although the question at hand was whether to submit the fields of testing hand-out for inclusion on the NELAC Internet site, it was suggested that it would be premature to submit the information without first discussing what will constitute a minimum list of fields of testing. In response to a request for suggestions as to the appropriate committee, participants proposed the development of a subcommittee from several committees. The Transition, Proficiency Testing, Program Policy and Structure, and On-site Assessment Committees were mentioned as possible candidates. Dr. Kircher suggested presenting the matter

to the Conference as an unresolved issue as to what constitutes the full scope of accreditation under program-method-analyte and to refer it to the NELAC Board of Directors for submission to the appropriate committee. This suggestion met with consensus approval from the committee.

NEW BUSINESS

The committee entertained a motion that they present a formal recommendation that NELAP ensure that the necessary infrastructure exists to support the NELAC Standards before taking action to implement them. This motion generated considerable committee discussion. Committee members representing a laboratory perspective emphasized the need for finite guidelines so that laboratories know what is expected of them. They suggested effecting clearly-stated transition rules to deal with any short-falls in the process and prioritizing problematic issues. Committee members presenting a regulatory perspective expressed the grave concern that making this recommendation would stop the process of implementation. They noted that the process will necessitate a phase-in period and that the full implementation of some parts of the program will take longer than others. An alternate motion was made that the Regulatory Coordination Committee formally recommend that the Transition Committee define problems of implementation before September 30, 1999, in order to identify points of conflict. Continued discussion of the issue generated the suggestion that the Regulatory Coordination Committee itemize and prioritize issues that are most critical to implementation as set forth below:

1. Scope of accreditation
2. Availability of PT samples
3. Technical training for auditors and availability of standard on-site checklists
4. Education of laboratories to be accredited (particularly “small” laboratories)

In concluding discussion, Dr. Kircher noted that the Regulatory Coordination Committee is not charged to resolve this issue. He made a suggestion that the issue be presented as an unresolved issue to the Conference in the Fifth Annual Meeting’s closing plenary and that the appropriate committee is admonished to address these critical issues. This suggestion met with unanimous approval from the committee.

CONCLUSION

There being no further new business to discuss, it was moved and seconded that the meeting be adjourned.

Attachment A

ACTION ITEMS
REGULATORY COORDINATION COMMITTEE MEETING
JUNE 29, 1999

Item No.	Action	Date to be Completed
1.	Committee will review EPA October 1999 Regulatory Agenda.	NELAC Vi
2.	Dr. Kircher will request that the USEPA regulatory agenda be posted on the NELAC Website.	
3.	The committee will present the issue of minimum fields of testing to the Conference for resolution.	
4.	The committee will present the issue of implementation infrastructure to the Conference for resolution.	

Attachment B

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REGULATORY COORDINATION COMMITTEE MEETING
JUNE 29, 1999

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